DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 29, 2014

Synthes (USA) Products LLC
Ms. Kara A. R. Elkin
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K141796
Trade/Device Name: DePuy Synthes TOMOFIX Osteotomy System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: August 1, 2014
Received: August 4, 2014

Dear Ms. Elkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141796

Device Name
DePuy Synthes TOMOFIX Osteotomy System

Indications for Use *(Describe)*

The DePuy Synthes TOMOFIX Osteotomy System is intended for osteotomies, treatment of bone and joint deformities, fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the distal femur and proximal tibia.

Specifically,

- The TOMOFIX Medial Proximal Tibia Plates are indicated for open- and closed-wedge osteotomies fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the medial proximal tibia
- The TOMOFIX Lateral Proximal Tibia Plates are indicated for open- and closed-wedge osteotomies, fixation of fractures and malalignment caused by injury or disease, such as osteoarthritis, of the lateral proximal tibia
- The TOMOFIX Lateral Distal Femur Plates are indicated for open-and closed-wedge osteotomies, fixation of fractures and malalignment caused by injury or disease, such as osteoarthritis, of the lateral distal femur
- The TOMOFIX Medial Distal Femur Plates are indicated for closed-wedge osteotomies, fixation of fractures and malalignment caused by injury or disease, such as osteoarthritis, of the medial distal femur

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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5.0 **510(k) Summary**

Sponsor: DePuy Synthes
1301 Goshen Parkway
West Chester, PA 19380

Phone: (610) 719-1239
Fax: (484) 356-9682

Contact Person: Kara A. R. Elkin
Date Prepared: August 1, 2014

Device Name: DePuy Synthes TOMOFIX Osteotomy System

Classification: Product Code – HRS, Plate, Fixation, Bone, Class II, §888.3030 – Single / multiple component metallic bone fixation appliance and accessories.

Predicate Devices: Synthes TOMOFIX Medial Distal Femur Plates (**K081353**)

Synthes TOMOFIX Osteotomy System (**K023941**)

Synthes Large Fragment Dynamic Compression Locking System (**K000682)**

Device Description: The DePuy Synthes TOMOFIX Osteotomy System consists of five different titanium plate families with locking and combination locking/compression holes. This system features plates designed to provide stable fixation of osteotomies of the distal femur and proximal tibia.

The DePuy Synthes TOMOFIX Medial Distal Femur Plates are part of the DePuy Synthes TOMOFIX Osteotomy System used for closed wedge femoral osteotomies. The subject plates are anatomically contoured to fit the medial distal femur, are available in right and left versions, as well as sterile and non-sterile.

Intended Use: The DePuy Synthes TOMOFIX Osteotomy System is intended for osteotomies, treatment of bone and joint deformities, fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the distal femur and proximal tibia.

Specifically,

- The TOMOFIX Medial Proximal Tibia Plates are indicated for open- and closed-wedge osteotomies fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the medial proximal tibia
- The TOMOFIX Lateral Proximal Tibia Plates are indicated for open- and closed-wedge osteotomies fixation of fractures,

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and malalignment caused by injury or disease, such as osteoarthritis, of the lateral proximal tibia
- The TOMOFIX Lateral Distal Femur Plates are indicated for open- and closed-wedge osteotomies fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the lateral distal femur
- The TOMOFIX Medial Distal Femur Plates are indicated for closed-wedge osteotomies fixation of fractures, and malalignment caused by injury or disease, such as osteoarthritis, of the medial distal femur

Substantial Equivalence:

The intent of this submission is to update the indications for use statement of the DePuy Synthes TOMOFIX Osteotomy System (cleared under K023941) by specifying osteotomy type (open or closed) and specific anatomical region indicated for each plate family in the system. Information has been provided to support the use of the DePuy Synthes TOMOFIX Osteotomy System for the proposed indications to support a substantially equivalent decision in comparison to the predicate Synthes TOMOFIX Osteotomy System as cleared under K023941.

It is also the intent of this submission to modify the design of the DePuy Synthes TOMOFIX Medial Distal Femur Plate. Information presented supports substantial equivalence of the DePuy Synthes TOMOFIX Medial Distal Femur Plate to the predicate devices, Synthes TOMOFIX Medial Distal Femur Plates **(K081353),** Synthes TOMOFIX Osteotomy System **(K023941)** and Synthes Large Fragment Dynamic Compression Locking System (**K000682).** The proposed plates have similar indications for use, design characteristics, materials, and incorporate the same fundamental technology.

Performance Data

Static and dynamic construct testing was completed for the plates included in the DePuy Synthes TOMOFIX Osteotomy System in order to demonstrate comparable mechanical performance to the predicates. The mechanical testing was designed to assess the stiffness and fatigue strength of the subject devices. The following tests and analyses were performed:

- **Axial Testing** - conducted by mounting the plates on an osteotomized sawbone femur model and subjecting the plates to an axial load
- **Torsion Testing -** conducted by mounting the plates on an osteotomized sawbone femur model and subjecting the plates to a torsional load
- **Bending Stiffness –** ProEngineer CAD software was used to calculate and compare stiffness properties in the critical cross section of the plates

- **Dynamic (Fatigue) Testing** – conducted by mounting the plate-screw constructs on POM-C test blocks with a milled surface to match the bottom of the plate and introducing a cyclical axial force

The results of the mechanical testing and engineering analyses demonstrate substantial equivalence.